REMARKS

This is in response to the outstanding action dated June 16, 2005. The Examiner objected to the specification because the continuing information on the first page did not match the information in the Declaration. Applicant advises the Examiner that the information that was in paragraph [0001] of the specification was present when the application was filed as a PCT application. During the International Phase, the International Office indicated that the priority claim was inappropriate and the Applicant amended the PCT papers to reflect priority only from US Provisional Application Ser. No. 60/184,299, filed Feb. 23, 2000. The specification was not amended at that time. On filing the National Phase US Application, the Declaration and Power recited only this provisional application. Thus, Applicant has now amended paragraph [0001] to recite claiming the benefit of only the Provisional Application US 60/184,299. As such, the objection is overcome.

Claims 27 and 36 were rejected on formal grounds for being unclear (claim 27) and lack of antecedent basis (claim 36). Claim 27 inadvertently recited the same value as both endpoints of a range. Applicant has now amended claim 27 to recite that the anodized layer thickness is between 0.3 mils and 0.5 mils. Support can be seen in the other claims as well as in the original claims. Claim 36 was rejected for lack of antecedent basis regarding the term "second retainer plate". The Examiner graciously pointed out that the term first appears in claim 73. As such, Applicant has amended the dependency of claim 36 so as to depend on claim 73. Therefore, there is now adequate antecedent basis for this term in claim 36 as currently amended.

All of the claims were rejected over Deeds in view of Miller and Feldman. All of the claims were also rejected for obviousness double patenting over Applicant's own US 6,589,477 in view of Feldman and provisionally for obviousness double patenting over co-pending application US 10/295,758 in view of Feldman.

Applicant wishes to point out to the Examiner that the present invention is the finding that an a maximum thickness of an anodic coating of 0.5 mils on an aluminum substrate sterilization container is critical to having the container adequately work in gas plasma sterilization. Containers without the anodic coating are subject to attack by the sterilization media, thereby limiting the number of cycles that the sterilization container may be appropriately used. Containers having anodic thicknesses greater than 0.5 mils interfere with the plasma field generation to such an extent that the containers with such coatings do not adequately achieve sterilization.

The Examiner cited Deeds for the recitation of a container used in sterilization, having vent holes, which are offset from each other, further having filters and filter retaining means covering the vent holes, and having a silicone gasket separating the lid from the bottom. Applicant wishes to point out that nowhere does Deeds point out the container material at all. Applicant's container is aluminum carrying an anodic layer of not greater than 0.5 mils.

The Examiner combines this with Miller and argues that Miller is directed to anodized m containers used in sterilization. In fact, Miller does not relate to containers as in applicant's invention, but rather to instrument trays for placing in otherwise commercially available containers. Note that the reason for application of the anodized coating to the Miller tray is to protect those surfaces from the sterilization media. The tray is not present for the purpose of generating or maintaining the electric field effect for the plasma. In contrast, the container of the present invention is critical to the present invention maintaining the electric field effect for plasma sterilization to work. Hence, there is no motivation for arriving at the present invention from the combination of Deeds and Miller. At most, Miller might suggest that anodizing the aluminum will protect the aluminum surfaces, but since there is no indication that layers of the thickness claimed by Applicant are of any import, one of ordinary skill is merely taught to utilize protective layer thicknesses in general.

The Examiner next relies on Feldman for showing the use gas plasma to sterilize anodized aluminum medical instruments. Here, the aluminum instruments are not involved in the creating or maintaining the electric field effect essential to gas plasma sterilization. Rather, the anodic layer is present to protect the aluminum instruments from being attacked by the sterilization media. Again, as in Miller, the most that can be said is that the secondary references each teach that anodic layers protect the aluminum surface from attack by the sterilant. There is no indication that there is a critically important level of anodic thickness for containers that will be suitable for the purpose that the container must provide.

The Examiner apparently recognizes this in the last paragraph of the 35 USC 103 rejection bridging pages4-5 of the outstanding Office Action, but indicates that they clearly disclose that such coatings are thin and one would not want a coating of a thickness that would interfere with the operation of the apparatus. Based on this, the Examiner asserts that it is mere routine experimentation to determine the optimal thicknesses. First, Applicant does not see where the references that mention anodic coatings specify "thin coatings". Secondly, the maximum coating thickness limitation in applicant's claim is 0.5 mils, i.e., 0.0005 inches or 12.7 microns thick. Even if the reference does indicate "thin layers" is 1 mil (0.001 inches or 25 microns) not a thin layer? Yet this is not suitable for Applicant's invention. There is nothing in the references that would indicate that an anodic layer coated container would work in gas plasma sterilization. The view that the finding of a protective layer that has adequate field effect for sterilization in gas plasma settings is routine experimentation presupposes that one would have expected such a result and merely had to tinker to find it. Yet the art of record does not provide such. For all anyone knew at the time the invention was made, any anodic layer would so interfere with the gas plasma sterilization process that insufficient sterilization would result. Such hindsight rejections are improper and cannot stand.

Furthermore, anodized aluminum has been mentioned in the context of sterilization containers since 1977 (although not in the context of gas plasma sterilization). In the

course of conducting further investigations, the undersigned conducted a search in the USPTO database in May 2005 and found 25 references, one of which is applicants copending case (discussed below). 5 references already of record (US 4,909,995 Jacob; US 5,384,103 Miller; US 5,741,460 Jacob, et al; US 5,897,831 Jacob, et al; and US 2003/0118491 Frieze et al) mention anodized aluminum in the context of sterilization containers; however, only Applicant's own copending application (US 2003/0118491) mentions anything about the anodization layer thickness.

The 25 references are included in the enclosed Information Disclosure Statement, and are listed here for the examiner's convenience.

1. US 4,046,254 Kramer
2. US 4,762,688 Berry Jr.
3. US 4,818,488 Jacob
4. US 4,898,715 Jacob
5. US 4,917,586 Jacob
6. US 4,931,261 Jacob
7. US 4,943,417 Jacob
8. US 4,976,920 Jacob
9. US 5,087,418 Jacob
10. US 5,171,525 Jacob
11. US 5,174,453 Stoeffler
12. US 5,200,158 Jacob
13. US 5,271,893 Newman
14. US 5,290,511 Newman
15. US 5,302,343 Jacob
16. US 5,393,490 Jacob
17. US 5,451,368 Jacob
18. US 6,149,878 Jacob
19. US 6,342,187 Jacob, et al
20. US 6,402,964 Schmid
21. US 6,605,252 Omasa
22. US 6,867,393 Lewis
23. US 6,884,393 Hui, et al
24. US 2002/0159915 Zelina, et al
25. US 2001/0036429 Gagele

Of these 25 references, only 2 mention anything about the anodized layer thickness, namely, reference 21 (US 6,605,252 Omasa) and reference 23 (US 6,884,393 Hui, et a).

Reference 21 does mention anodized aluminum in the context of sterilization apparatus and further mentions having prepared and tested such apparatus with anodized layer thicknesses both within and beyond the limitations set forth in one or more of Applicant's claims. However, this reference has a filing date of January 16, 2001. The present invention however, has a filing date of February 14, 2001, but claims benefit of US Provisional Application 60/184299, filed February 23, 2000, almost a year before the filing date of Reference 21. Thus, this reference is not prior art to the present application.

Reference 23 does mention both anodized aluminum in connection with sterilization apparatus and that the anodidization layer should be within the ranges set forth in Applicant's claims. However, Reference 23 has a filing date of July 13, 2001, which is 5 months after Applicant's filing date under the PCT of February 14, 2001. Thus, this reference is not prior art to the present application.

Thus, none of the newly submitted art is suitable upon which to base a rejection of the present claims.

The Examiner's premise for the present rejections has been that finding the "appropriate" anodization layer thickness" was routine experimentation. However, the only references to actually mention anything about anodization layer thicknesses are documents that have effective filing dates after that of Applicant's invention.

Gas plasma sterilization apparatus has been available since before 1987. Feldman (US 5,658,529, relied upon by the Examiner) mentions that gas plasma sterilization was discussed in Jacobs US 4,643,876, issued 2/17/1987. Thus, even as late as the present invention provisional filing date (2/23/2000), gas plasma sterilization was known for 13 years. Yet in 13 years, there is no mention of any criticality of an anodization layer thickness that is at once protective of the aluminum and at the same time permits adequate electric field effect to permit the plasma sterilization reaction to adequately proceed. This

represents a long felt need in the gas plasma sterilization industry, a result which Applicant's invention has suitably met. It is clear black-letter patent law that meeting a long felt, but unmet need defines unobviousness. 13 years is clearly unduly long if the solution were mere routine experimentation. It is not the specific experimentation itself that is the benchmark of unobviousness, but the recognition that a solution may be found in a particular set of experimentation and then conducting that experimentation. Here, the art had not even considered the possibility of an anodized layer thickness limitation on sterilization containers that would both be protective of the aluminum and simultaneously permit the electric field effect necessary to obtaining adequate gas plasma sterilization. Thus, Applicant's invention is indeed unobvious over the prior art and is of patentable merit.

Based on the foregoing, Applicant submits that the present invention is in condition for allowance and respectfully requests that the examiner pass it to issue.

Respectfully submitted,

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